



**CIRCULATORY SYSTEM DEVICES PANEL
AGENDA*****May 6, 2014*****Circulatory System Devices Panel
Advanced Circulatory Systems, Inc. RESQCPR System
Gaithersburg Hilton**

On May 6, the committee will discuss, make recommendations and vote on information related to the premarket approval application for the RESQCPR System sponsored by Advanced Circulatory Systems, Inc. The RESQCPR System is comprised of two devices: the RESQPOD 16.0 Impedance Threshold Device (ITD), and the RESQPUMP Active Compression Decompression CPR (ACD-CPR) Device. These devices are used together during manual CPR in an attempt to enhance venous return to the heart and blood flow to vital organs during CPR to ultimately increase survival and neurologic outcome in patients suffering from out of hospital cardiac arrest.

8:00 a.m.	Call to Order Introduction of Committee	Richard Page, M.D. Chairperson
	Conflict of Interest Statement	Jamie Mae Waterhouse, M.B.A. Designated Federal Officer
8:15 a.m.	Sponsor Presentation	
9:45 a.m.	Sponsor Q&A	
10:00 a.m.	Break	
10:15 a.m.	FDA Presentation	
11:45 a.m.	FDA Q&A	
12:00 p.m.	Lunch	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Panel Deliberations	
3:15 p.m.	Break	
3:30 p.m.	FDA Questions to the Panel	
5:00 p.m.	FDA and Sponsor Summations	
5:30 p.m.	Panel Vote	
6:00 p.m.	Adjournment	

*** Open Public Hearing** – Interested persons may present data, information, or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, the Chair may ask them to remain if the panel wishes to question them. Then the Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.